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510(k) Summary as required by section 807.92(c)

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: May 12, 2010

Applicant: Memometal Technologies
c/o Mr. Gilles Audic
Quality Manager
Rue Blaise Pascal
Campus De Ker Lann
Bruz, France 35170
332-99-055066
U.S.A. Contact: Joe Clift
(901) 680-6221

MAY 19 2010

Common Name:	Subtalar Arthroereisis Implant
Device Trade Name:	SubFix Arthroereisis Implant
Device Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3040
Product Code:	HWC
Predicate Devices:	K960692 KMI Subtalar MBA® Arthroereisis Implant (now owned by Intregra) K031155 Osteomed Talar-Fit™ Subtalar Arthroereisis Implant K032902 Nexa Orthopedics, INC Subtalar K041289 Arthroereisis Implant Talus of Vilex (TOV) K080280 Instratek, INC.Sub-Talar Lok, Model 7-11 mm K792670 Wright Medical Smith Sta-Peg K033046 Nexa Orthopedics Subtalar Peg ASI K051611 KMI MBA™ Resorb K071456 Arthrex Pro Stop Plus
Registration Number:	3004082045
Owner Operator Number:	9096224

Device Description:

The Memometal Implant is a one-piece device made of medical grade Titanium Alloy, Ti6Al4V. The implant is available in 5 sizes ranging from 6.5 mm to 11.5 in diameter. No new materials or processes are used in the development of this implant.

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Indications for Use:

The Memometal Technologies' SubFix Arthroereisis Implant is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus blocking excessive pronation and the resulting sequela.

The SubFix Arthroereisis Implants are intended for single use only.

Comparison to Predicate Device:

The Memometal device has numerous similarities to the predicate devices which are summarized here. The SubFix device and predicate devices K960692 KMI Subtalar MBA® Arthroereisis Implant (now owned by Intregra) and K031155 Osteomed Talar-Fit™ Subtalar Arthroereisis Implant have the same indications for use and share technical characteristics of being cannulated, threaded screw implants. Each device is placed into the sinus tarsi of the foot, allowing subtalar joint motion while blocking excessive pronation. Most systems are cannulated for ease of implantation. The SubFix device and predicate device K032902 Nexa Orthopedics, INC Subtalar are comparably sized. The SubFix device and predicate devices K041289 Arthroereisis Implant Talus of Vilex (TOV) K080280 Instratek, Inc. Sub-Talar Lok, Model 7-11 mm have similar characteristics of being is titanium color anodized.

Performance Data:

An engineering analysis and a material comparison to various predicate devices were used to help demonstrate equivalence.

Summary:

The Memometal device and the predicate devices have the similar design characteristics and intended use. The new device is substantially equivalent to the predicate devices and should not introduce new concerns in terms of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Memometal Technologies
% Mr. Gilles Audic
Rue Blaise Pascal
Campus De Ker Lann
Bruz, France 35170

MAY 19 2010

Re: K093820
Trade/Device Name: SubFix Arthroereisis Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 31, 2010
Received: April 16, 2010

Dear Mr. Audic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

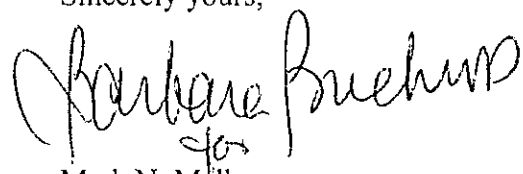
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093820
Device Name: SubFix Arthroereisis Implant
Indications for Use:

The Memometal Technologies' SubFix Arthroereisis Implant is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing subtalar joint motion but blocking excessive pronation and the resulting sequela.

The SubFix Arthroereisis Implants are intended for single use only.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices